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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,129	12/15/2005	Premindra Anthony Chandraratna		5559

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EXAMINER

BOR, HELENE CATHERINE

ART UNIT	PAPER NUMBER
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3768

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/562,129

Applicant(s)

CHANDRARATNA, PREMINDRA
ANTHONY

Examiner

Helene Bor

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/15/2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 161. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claim 1-3, 6-9, 11, 17-18 & 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Huckle'849 et al. (US Patent Application No. 2003/0153849 A1).

Claim 1: Huckle'849 teaches a therapeutic ultrasound device (Abstract).

Huckle'849 teaches positioning a substrate [such as spandex] on the body surface of a human (Page 2, Para 0022). Huckle'849 teaches a plurality of ultrasound transducer elements disposed on the face of the substrate [covering member] (Page 8, Para 0109 & Page 6, Para 0086). Huckle'849 teaches the device being structured to be effective to deliver ultrasound energy to tissues in mammals for a sufficient time [duration] to stimulate angiogenesis and/or relieve ischemia (Page 2, Para 0021).

Claim 2/1: Huckle'849 teaches the substrate [covering member] comprises a flexible sheet [elastic or stretchable fabric] (Page 8-9, Para 0109).

Claim 3/1: Huckle'849 teaches drive electronics for controlling operation [Main Operating Unit, MOU] of at least some of the transducer elements (Page 6, Para 0086).

Claim 6/1: Huckle'849 teaches the transducer elements are rigidly connected together (Figure 11B & Page 8, 0106).

Claim 7/1 & 8/1: Huckle'849 teaches the device being configured to cover a portion of a human chest (Figure 14A) and configured to cover a portion of a human leg (Figure 9).

Claim 9: Huckle'849 teaches a method for causing an ultrasound-induced effect within the body of a human or veterinary patient (Abstract). Huckle'849 teaches positioning an ultrasound device including a plurality of flexibly connected ultrasound transducer elements on the body surface of the patient (Page 6, Para 0086).

Huckle'849 teaches using the ultrasound transducer elements to deliver ultrasound to at

Art Unit: 3768

least a portion of the patient's body for sufficient time to cause the ultrasound-induced effect (Page 2, Para 0021).

Claim 11/9: Huckle'849 teaches a method wherein the ultrasound has a frequency in the range of about 1 MHz to about 2 MHz (Page 6, Para 84).

Claim 17/9: Huckle'849 teaches a method wherein the ultrasound-induced effect is angiogenesis and/or treatment or prevention of ischemia (Claim 46 & 47).

Claim 18/9: Huckle'849 teaches a method wherein the ultrasound device is positioned on the chest (Page 6, Para 0086 & Page 4, Para 0068) and used to promote angiogenesis in the heart for relief of myocardial ischemia (Claim 46 & 47).

Claim 22/9: Huckle'849 teaches a method wherein the ultrasound device is positioned on the patient's calf (Figure 11B & 11C) and used to promote angiogenesis, relieve myocardial ischemia or other ischemic condition of the leg (Claim 46 & 47).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claim 4-5, 10, 13-16, 19-20 & 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huckle'849 et al. (US Patent Application No. 2003/0153849 A1), and further in view of Horzewski'009 et al (US Patent Application No. 2004/0153009 A1).

Claim 4/1 & 5/1: Huckle'849 fails to teach the piezoelectric nature of the transducer elements. However based on the applicant's disclosure on Page 8, Line 25-30, the applicant states, "Such materials [PZT-based piezoelectric ceramic] and methods for making such individual transducer elements having desirable properties for insonating tissues are well known in the art." The claims are thus rejected based on applicant's own admission. In addition, Horzewski'009 teaches transducer elements comprising piezoelectric ceramic material and PZT (Page 3, Para 0044). It would have been obvious to one of ordinary skill in the art to combine the teachings of Huckle'849 and Horzewski'009 in order to convert the electrical energy into acoustic energy in the form of mechanical vibrations (Page 3, Para 0047).

Claim 10/9: Huckle'849 teaches a method to effectively deliver ultrasound energy to tissues in mammals for a sufficient time [duration] to stimulate angiogenesis and/or relieve ischemia (Page 2, Para 0021). Huckle'849 do not specifically teach an exact length of time. Huckle'849 teaches a predetermined amount of time (Page 7, Para 0092). However, for more details regarding a specific length of time Horzewski'009 teaches a prescribed maximum treatment time, e.g. 60 minutes or in other words one hour (Page 7 See Table). It would be obvious of one of ordinary skill in

Art Unit: 3768

the art to combine the teachings of Huckle'849 and Horzewski'009 in order to monitor the treatment time (Page 9, Para 0115) and to protect the patients from the potential adverse consequences (Page 7, Para 0099).

Claim 13-16/9 & 25-27/9: Huckle'849 teaches a main operating unit (MOU) to control the signals to the ultrasound transducers (Page 6, Para 0086). Huckle'849 fails to go in-depth regarding how the MOU controls the signals to the ultrasound transducers. However, Huckle'849 incorporates herein by reference US Patent No. 5,556,372 by Talish'372 et al., which has the MOU with preprogrammed treatments and a signal monitoring circuit for frequency, pulse repetition frequency and the pulse width (Talish'372, Col. 4, Line 58 – Col. 5, Line 53). In further review of Horzewski'009, the reference teaches a method wherein a controller can operate a given transducer at a prescribed power level, which can remain fixed or can be varied during the treatment session. Horzewski'009 also teaches the controller operating one or more transducers within an array of transducers (or when using multiple applicators) at different power levels, which can remain fixed or themselves varied over time (Page 6, Para 0087). It would have been obvious to one of ordinary skill in the art to combine the teachings of Huckle'849 and Horzewski'009 in order to achieve the optimal application of acoustic energy and the optimal therapeutic effect (Page 5, Para 0070).

Claim 19/9: Huckle'849 fails to teach a method wherein the ultrasound device is used to cause thrombolysis. However, Horzewski'009 teaches the ultrasound device is used to cause thrombolysis in the patient (Page 9, Para 0120). It would have been

Art Unit: 3768

obvious to one of ordinary skill in the art to combine the teachings of Huckle'849 and Horzewski'009 in order enhance the therapeutic effect (Page 9, Para 0118).

Claim 20/9: Huckle'849 teaches a method specifically for a patient with a myocardial infarction. However, Horzewski'009 teaches the patient is presenting with myocardial infarction (Page 2, Para 0023). It would have been obvious to one of ordinary skill in the art to combine the teachings of Huckle'849 and Horzewski'009 in order in order to increase tissue perfusion of selected tissues (Page 2, Para 0025) and for the patient to receive the benefits of the treatment (Page 1, Para 0004).

Claim 23/9: Huckle'849 teaches a method wherein the ultrasound device is positioned on the chest (Page 6, Para 0086 & Page 4, Para 0068) and used to promote angiogenesis in the heart for relief of myocardial ischemia (Claim 46 & 47). Huckle'849 does not specifically teach using the ultrasound device on patients suffering from dilated cardiomyopathy [weakened heart muscle by disease]. However, Horzewski'009 teaches using an ultrasonic device to treat weakened heart muscles (Page 10, Para 0311). It would have been obvious to one of ordinary skill in the art to combine the teachings of Huckle'849 and Horzewski'009 in order in order to improve heart wall motion or function (Page 10, Para 0131).

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huckle'849 et al. (US Patent Application No. 2003/0153849 A1), and further in view of Kawabata'387 et al (US Patent No. 7,125,387 B2).

Claim 12/9: Huckle'849 teaches an ultrasound frequency range of about 1 MHz to about 2 MHz (Page 6, Para 0084) and thus fails to fall with the ranged claimed.

Art Unit: 3768

However, Kawabata'387 teaches a device that has a basic frequency range of 20 kHz to 1 MHz (Col. 8, Line 54-60). It would have been obvious to one of ordinary skill in the art to combine the teachings of Huckle'849 and Kawabata'387 in order to enhance the quality of life for a patient (Col. 1, Line 13-19).

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huckle'849 et al. (US Patent Application No. 2003/0153849 A1), and further in view of Bukshpan'568 et al (US Patent Application No. 2002/0111568 A1).

Claim 21/9: Huckle'849 fails to teach the method wherein the ultrasound device is used to prevent restenosis after angioplasty or the placement of a stent in a coronary artery or other vessel. However, Bukshpan'568 teaches a method wherein the ultrasound device is used for ablating tissue to prevent restenosis and use for the placement of stents (Page 6, Para 0039 - 0040).

9. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huckle'849 et al. (US Patent Application No. 2003/0153849 A1), and further in view of Talish'070 et al (US Patent No. 6432070 B1).

Claim 24/9: Huckle'849 teaches an ultrasound device used to promote angiogenesis (Page 2, Para 0021) on the extremity of a patient (Figure 1). Huckle'849 fails to teach the device for use with patients suffering from neuropathy [as defined by Merriam-Webster as "an abnormal and usually degenerative state of the nervous system"]. Talish'070 teaches an ultrasound device used to treat patients suffering from a reflex sympathetic dystrophy [RSD], which is a disease of the sympathetic nervous system (Col. 1, Line 60 – Col. 2, Line 7). It would have been obvious to one of ordinary

skill in the art to combine the teachings of Huckle'849 and Talish'070 in order to successful treat the patient (Col. 2, Line 18-41).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. Coffey, Kenneth W. et al. APPARATUS AND METHOD FOR SUBSTANTIALLY STATIONARY TRANSDUCER THERAPEUTIC ULTRASOUND TREATMENT, 07/31/2003. US 20030144611 A1.
- b. Miwa, Hirohide et al. Ultrasonic irradiation apparatus, 07/17/2003. US 20030135135 A1.
- c. Talish; Roger J. et al. Method and apparatus for ultrasonic treatment of reflex sympathetic dystrophy, 08/13/2002. US 6432070 B1.
- d. Redding, Bruce K. JR. Ultrasonically enhanced substance delivery method, 10/24/2002. US 20020156414 A1.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Bor whose telephone number is 571-272-2947. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3768

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

hcb


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